4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Babson Diagnostics, Inc., for the Babson Diagnostics aC19G1, and Twist Bioscience Corporation for the SARS-CoV-2 NGS Assay. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by each Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The Authorization for the Babson Diagnostics aC19G1 is revoked as of February 14, 2023. The Authorization for the SARS-CoV-2 NGS Assay is revoked as of February 14, 2023.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993-0002, 301-796-0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On June 23, 2020, FDA issued the Authorization to Babson Diagnostics, Inc., for the Babson Diagnostics aC19G1, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On March 23, 2021, FDA issued the Authorization to Twist Bioscience Corporation for the SARS-CoV-2 NGS Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on July 23, 2021 (86 FR 39040), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorization Revocation Requests

In a request received by FDA on February 7, 2023, Babson Diagnostics, Inc., requested the revocation of, and on February 14, 2023, FDA revoked, the Authorization for the Babson Diagnostics aC19G1. Because Babson Diagnostics, Inc., notified FDA that it is no longer offering the Babson Diagnostics aC19G1and requested FDA revoke the Babson Diagnostics

aC19G1, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on January 27, 2023, Twist Bioscience Corporation requested withdrawal of, and on February 14, 2023, FDA revoked, the Authorization for the SARS-CoV-2 NGS Assay. Because Twist Bioscience Corporation notified FDA that it will no longer be using the SARS-CoV-2 NGS Assay and requested FDA withdraw the Authorization for the SARS-CoV-2 NGS Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at https://www.regulations.gov/.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Babson Diagnostics, Inc., for the Babson Diagnostics aC19G1 and of Twist Bioscience Corporation for the SARS-CoV-2 NGS Assay. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

February 14, 2023

Jane Hughie
Director, QA/RA
Babson Diagnostics
1205 Sheldon Cove, Suite 2-J
Austin, TX 78753

Re: Revocation of EUA200682

Dear Jane Hughie:

This letter is in response to the request from Babson Diagnostics, Inc., received via email on February 7, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Babson Diagnostics aC19G1 issued on June 23, 2020, and amended on September 23, 2021. Babson Diagnostics, Inc., indicated that they no longer offer the Babson Diagnostics aC19G1 and requested that the EUA be revoked.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Babson Diagnostics, Inc. has requested FDA revoke the EUA for the Babson Diagnostics aC19G1, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200682 for the Babson Diagnostics aC19G1, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Babson Diagnostics aC19G1 is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

February 14, 2023

Shakil Ahmed
Sr. Director, Regulatory Affairs and Quality Assurance
Twist Bioscience Corporation
681 Gateway Blvd.
South San Francisco, CA 94080

Re: Revocation of EUA202029

Dear Shakil Ahmed:

This letter is in response to the request from Twist Bioscience Corporation, received via email on January 27, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 NGS Assay issued on March 23, 2021, amended on June 25, 2021, and September 23, 2021, and reissued on July 28, 2022. Twist Bioscience Corporation indicated that they no longer plan to continue marketing the SARS-CoV-2 NGS Assay and requested that the EUA be withdrawn. FDA understands that no SARS-CoV-2 NGS Assay reagents associated with this EUA are available to the United States market.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Twist Bioscience Corporation has requested FDA withdraw the EUA for the SARS-CoV-2 NGS Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202029 for the SARS-CoV-2 NGS Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 NGS Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: March 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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